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*Published in:*  
Journal of Evaluation in Clinical Practice

*DOI:*  
[10.1111/j.1365-2753.2010.01466.x](https://doi.org/10.1111/j.1365-2753.2010.01466.x)

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*Document Version*  
Publisher's PDF, also known as Version of record

*Publication date:*  
2011

[Link to publication in University of Groningen/UMCG research database](#)

*Citation for published version (APA):*

Fokkens, A. S., Wiegersma, P. A., Beltman, F. W., & Reijneveld, S. A. (2011). Structured primary care for type 2 diabetes has positive effects on clinical outcomes. *Journal of Evaluation in Clinical Practice*, 17(6), 1083-1088. <https://doi.org/10.1111/j.1365-2753.2010.01466.x>

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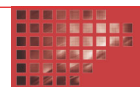
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## Structured primary care for type 2 diabetes has positive effects on clinical outcomes

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### Keywords

clinical outcome, diabetes mellitus, evaluation study, patient care team, primary health care, structured care

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Accepted for publication: 12 February 2010

doi:10.1111/j.1365-2753.2010.01466.x

### Abstract

**Background** Patients with type 2 diabetes have an increased risk of developing microvascular and macrovascular complications. In routine diabetes care an adequate reduction of risk factors for these complications is often not achieved.

**Objective** The aim of the study was to evaluate the effects of structured diabetes care on clinical outcomes of patients with type 2 diabetes in primary care.

**Methods** We performed a quasi-experimental study on the effects of structured care consisting of organizational and educational components ( $n = 581$ ) compared with care-as-usual ( $n = 152$ ). We assessed clinical outcomes of HbA1c, blood pressure, cholesterol, creatinine and body mass index, at baseline and after 1 year. The long-term effects in the structured care group were determined after another 2 years.

**Results** Structured care led to improvement in HbA1c and long-term improvements in blood pressure and cholesterol compared with care-as-usual. After 1 year, the percentage of patients who did not deteriorate was higher in the structured care group, again for HbA1c, diastolic blood pressure, low-density lipoprotein cholesterol and body mass index.

**Conclusions** Structured diabetes care consisting of multiple components has a positive effect on clinical outcomes compared with care-as-usual. Our findings support its further implementation in order to reduce complications in type 2 diabetes patients.

### Introduction

Patients with type 2 diabetes have an increased risk of developing microvascular and macrovascular complications. Several studies conclude that intensive glycaemic control and blood pressure control in type 2 diabetes reduces the risk of complications [1,2]. Hence, care should be aimed at reducing total cardiovascular risk by strict glycaemic, blood pressure and lipid control, and furthermore by encouraging lifestyle changes especially where weight control is concerned.

Although the evidence for the effects of reducing complication risk is convincing, this reduction is often not reached in routine diabetic care. Studies show that patients not only have poor metabolic control, but that laboratory measurements, patient education and behavioural activities are also not performed frequently enough [3,4]. Attempts have been made to organize care in such a way that it can achieve the high demands of diabetes care, using various care models and interventions. Many of these care models have focused on one or two main aspects, such as patient education, changes in cooperation or training of health care professional

[5–7]. Effective approaches for chronic diseases have often been multifaceted, involving different combinations of various types of education for the health care professionals, registration systems, organizational changes, doctor feedback and patient education and support [3,8,9]. A multifaceted approach may also be effective in diabetes care.

It is still unclear from research whether multifaceted care can be effective in everyday practice. Studies have only targeted a select group of patients, such as poorly controlled diabetes patients [10] or they have not been conducted in an everyday primary care setting. If multifaceted structured care (SC) is to be implemented more widely, then clearly more evidence is needed to establish its efficacy. Moreover, such evidence should be provided from studies that include the effects of a number of clinical outcomes, such as blood pressure, cholesterol and body mass index (BMI). To date, most studies have only used glycaemic control (measured by HbA1c) as the main outcome measure, even though this measure only accounts for part of the added cardiovascular risk [11,12].

In this study, we therefore assessed the effects of multifaceted diabetes care, consisting of a number of organizational and

educational components, on several clinical outcomes in a routine primary care setting. The aim of the study was to evaluate the effects of this structured diabetes care.

## Methods

### Design

This study involved a quasi-experimental study on the effects of SC compared with care-as-usual (CAU) on clinical outcomes. We collected clinical outcomes at baseline and after 1 year. The long-term effects in the SC group were subsequently determined for a further 2 years.

### Study population, practices and patients

General practices in the north of the Netherlands voluntarily participated in the SC intervention study from the beginning of 2003. At the time of data collection in 2006 the SC group consisted of 24 general practices, from which a total of 795 patients were sampled. Of these practices, 11 participated since 2003 or 2004. The length of follow-up differed as a consequence of the different enrolment time of the practices. For the CAU control group, practices were eligible

if they did not participate in a diabetes-specific care improvement programme and were located in a region comparable to that of the SC group. This CAU group consisted of 14 general practices that took part in another effect study. The intervention in that study could not affect our findings because it started after the completion of our data collection. In each practice, 15 patients diagnosed with type 2 diabetes were randomly sampled. These patients were subsequently informed; if they objected against anonymous data retrieval, a next patient was selected. The design of the study was agreed upon by the local Medical Ethics Committee.

### Intervention

The care was organized in accordance with the national clinical guidelines of the Dutch College of General Practitioners (Box 1) [13] in combination with a number of organizational and educational components. Organizational aspects consisted of multidisciplinary cooperation, a clear task division and cooperation between the general practitioner, diabetes specialized nurse, practice nurse and dietician (Box 2). Also, all relevant clinical parameters were registered in a structured registration programme called Diabcare, and used for comparisons within and between practices. The diabetes nurse discussed these parameters and process indicators with the general practitioner on an annual basis.

The educational component targeted both patients and health care professionals. The patients received individual education from a diabetes specialized nurse and a dietician. In addition, they received a 'diabetes passport' to record medication, laboratory results, treatment targets and personal information. The health care professionals took part in an education programme consisting of lectures on a number of relevant topics, such as neuropathy and diet.

### Care-as-usual

The practices included in the control group for the study provided diabetes CAU. CAU was based on the national guidelines of the Dutch College of General Practitioners, and consisted of four checks per year, involving three general and one more extensive checks a year (Box 1) [13].

### Measures

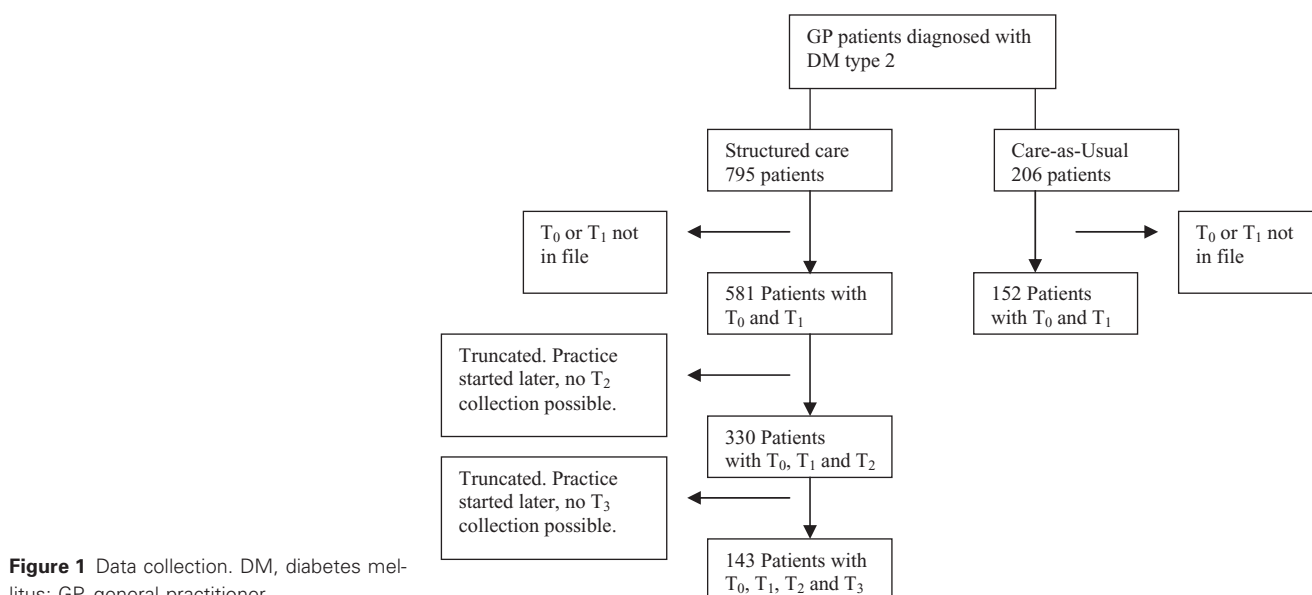
The following clinical outcomes were collected: glycosylated haemoglobin (HbA1c), total cholesterol, high-density lipoprotein

#### Box 1 Guidelines of the Dutch College of General Practitioners.

- 3-monthly checks
  - Inquire after: well-being; possible hypo- or hyperglycaemia; diet, exercise or medication difficulties
  - Determine: weight, fasting glucose
  - Patients on insulin (2–4 days): determine HbA1c and 4-point day curve.
  - Patients on hypertensive: determine blood pressure
  - High ulcer risk: feet examination
- Yearly check
  - Inquire after: vision difficulties, cardiovascular complaints, neuropathy and sexual problems
  - Determine: weight, blood pressure, fasting glucose, HbA1c, creatinine, lipids
  - Patients on insulin: inspection of injection places
  - Patients on diuretic or Renin-Angiotensin inhibitors: potassium
  - Patients with life expectancy >10 years: albumin/creatinine
  - Perform fundus photography

#### Box 2 Structured care components.

- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>• Organizational               <ul style="list-style-type: none"> <li>Multidisciplinary cooperation:</li> <li>Diabetes registration system:</li> </ul> </li> <li>• Educational               <ul style="list-style-type: none"> <li>Patient:</li> <li>Health care professional:</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>Clear task division and cooperation between general practitioner (GP), diabetes specialized nurse (DSN), practice nurse, dietician.</li> <li>Standardized reporting between care givers.</li> <li>Yearly structured entering of all diabetes relevant parameter.</li> <li>Comparisons possible within and between practices.</li> <li>Outcome and process indicators discussed by DSN with GP.</li> <li>According to protocol patient received education from DSN and dietician.</li> <li>Patient participation and knowledge was stimulated with use of the diabetes passport.</li> <li>All professionals could participate in the education programme.</li> </ul> |
|---|--|



**Figure 1** Data collection. DM, diabetes mellitus; GP, general practitioner.

cholesterol, creatinine, blood pressure and BMI. Low-density lipoprotein (LDL) cholesterol was estimated with the Friedewald formula [14]. LDL cholesterol was not estimated for patients with a triglyceride value above the 4.52 mmol L<sup>-1</sup> because the Friedewald formula then becomes less accurate.

In the SC group, clinical outcomes were collected from all patients registered in the registration programme, beginning from the time the practice participated the SC and annually for 3 years thereafter.

In each practice of the CAU group the clinical outcomes at baseline (2003) and after 1 year were manually extracted from the electronic medical records of 15 randomly selected type 2 diabetes patients using a structured electronic data entry form. A separate validation study showed good agreement for laboratory parameters between the two data sources and acceptable agreement for non-laboratory parameters [15].

## Statistical methods

First, response rates and characteristics of practices and patients were determined. Subsequently, using a two-sample *t*-test, comparisons were made between SC and CAU group for the changes between baseline and 1-year follow-up. Multiple regression analyses were used, with the change of the clinical outcomes being used as the outcome variables. The independent variables of baseline value, duration of diabetes, age, gender, insulin use and start year of the SC were added to the models. Linear mixed models were used for the repeated measurements. The sample was divided into two groups consisting of patients with deteriorated clinical outcomes and those with equal or improved clinical outcomes. Logistic regression was used to compare the SC and CAU group. Statistical analyses were performed with SPSS 14.0 and Mlwin 2.02. *P*-values <0.05 were considered significant.

## Results

In the SC group, data were collected from 581 patients (73%) with data both at baseline (T<sub>0</sub>) and after 1 year (T<sub>1</sub>). Data were collected

from 330 patients after 2 years (T<sub>2</sub>) from 143 patients after 3 years (T<sub>3</sub>). The main reason for the low number of patients at T<sub>3</sub> was that only four practices started the SC 3 years before the data collection (see Fig. 1). In the CAU group T<sub>0</sub> and T<sub>1</sub> data were available for 152 patients (74%).

The patients for whom there was no baseline and T<sub>1</sub> measurement were slightly older (67.9 vs. 65.5 years, *P* = 0.004), had a longer history of diabetes (6.9 vs. 5.0 years, *P* = 0.000), lower diastolic blood pressure (80.4 vs. 82.5 mmHg, *P* = 0.006), higher HbA1c (6.8 vs. 6.6, *P* = 0.04) and were more often female (60.5% vs. 49.9%, *P* = 0.005). They did not differ in mean BMI, systolic blood pressure, cholesterol, creatinine or insulin use.

## Practice and patient characteristics

The characteristics of the SC and CAU group practices and their patients were very similar, with only diabetes history showing a longer duration in the SC group (Table 1).

## Clinical outcomes

The adjusted change of HbA1c was significantly more favourable in the SC group than in the CAU group (Table 2). The adjusted LDL cholesterol was lower in the SC group by 0.2 mmol L<sup>-1</sup> after 1 year than in the CAU group, but this difference was not significant (*P* = 0.059) (Table 2). The adjusted changes of systolic and diastolic blood pressure were also more favourable in the SC group but did not reach significance (*P* = 0.073).

No differences between the SC and usual care group were found in the percentage of patients on insulin after 1 year. Both groups showed a patient increase of 5%.

Patients in the SC group had significantly higher adjusted odds for having an equal or improved outcome after 1 year on HbA1c, diastolic blood pressure, LDL cholesterol and BMI than patients in the usual care group (Table 3).

Assessment of the long-term effects of the SC showed a significant improvement in blood pressure and cholesterol (Table 4).

**Table 1** Baseline characteristics of practices and patients

	SC	CAU
Practices, <i>n</i>	24	14
Solo, <i>n</i> (%)	13 (54.2)	7 (50.0)
Duo, <i>n</i> (%)	6 (25.0)	5 (35.7)
Group, <i>n</i> (%)	5 (20.8)	2 (14.3)
Patients per practitioner	2234 (646)	1872 (603)
Diabetes patients	76.2 (32.1)	53.9 (30.3)
Patients under treatment internist, %	9.8 (7.4)	11.2 (4.9)
Practice nurse employed, %	68.4	63.6
Patients with 1-year follow-up ( <i>n</i> )	581	152
Age (years)	65.8 (11.9)	64.2 (11.5)
Male (%)	49.9	50.7
Insulin use (%)	14.6	15.1
Duration of diabetes (years)	5.2 (5.1)*	3.8 (4.0)*
Patients with also 2-year follow-up ( <i>n</i> )	330	—
Age (years)	64.7 (11.5)	—
Male (%)	48.5	—
Insulin use (%)	15.5	—
Duration of diabetes (years)	5.0 (4.9)	—
Patients with also 3-year follow-up	143	—
Age (years)	64.0 (11.7)	—
Male (%)	43.3	—
Insulin use (%)	17.5	—
Duration of diabetes (years)	4.2 (3.7)	—

\**P* < 0.05.

Data are means ± SD unless indicated otherwise.

CAU, care-as-usual; SC, structured care.

**Table 3** Comparison between structured care and care-as-usual group in having an equal or improved outcome after 1 year (adjusted odds ratio)

	<i>n</i>	OR <sup>†</sup>	95% CI
HbA1c (%)	474	1.80 <sup>a,c</sup>	1.03–3.14
Systolic BP (mmHg)	571	1.54 <sup>a,c</sup>	0.99–2.38
Diastolic BP (mmHg)	570	2.13 <sup>a</sup>	1.37–3.32
Total cholesterol (mmol L <sup>-1</sup> )	430	1.85 <sup>b,c</sup>	0.91–3.76
HDL cholesterol (mmol L <sup>-1</sup> )	432	1.22 <sup>a,e</sup>	0.65–2.29
LDL cholesterol (mmol L <sup>-1</sup> )	386	2.89 <sup>a</sup>	1.47–5.69
Creatinine (μmol L <sup>-1</sup> )	462	1.36	0.83–2.22
BMI (kg m <sup>-2</sup> )	382	2.48 <sup>a</sup>	1.36–4.46

\**P* < 0.05.<sup>†</sup>Adjusted for: <sup>a</sup>baseline values, <sup>b</sup>duration of diabetes, <sup>c</sup>age, <sup>d</sup>insulin use, <sup>e</sup>gender.

BMI, body mass index; BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

HbA1c remained stable after 3 years compared with baseline. A minor increase was found for creatinine after 1 and 2 years. BMI remained stable for the first 2 years, but a significant improvement was found after 3 years.

## Discussion

We found that SC leads to improvement in HbA1c and long-term improvements in blood pressure and cholesterol when compared

**Table 2** Comparison of clinical outcomes between the structured care (SC) and care-as-usual (CAU) group at baseline and adjusted difference after 1 year

	Baseline		Difference after 1 year		Adjusted difference between SC and CAU after 1 year	
	SC mean (SD)	<i>n</i>	SC mean (SD)	CAU mean (SD)	<i>n</i>	<i>P</i> -value
HbA1c (%)	6.5 (1.1)*	388	+0.2 (1.0)	+0.2 (1.4)	416	0.011
Systolic BP (mmHg)	146.1 (18.1)	443	-2.7 (18.4)*	+1.0 (18.0)*	571	0.073
Diastolic BP (mmHg)	82.4 (9.2)	442	-1.8 (9.2)	-0.4 (10.6)	570	0.073
Total cholesterol (mmol L <sup>-1</sup> )	4.9 (0.9)*	414	-0.2 (0.9)	-0.4 (1.2)	430	0.711
HDL cholesterol (mmol L <sup>-1</sup> )	1.3 (0.3)	432	+0.0 (0.2)	+0.0 (0.3)	386	0.676
LDL cholesterol (mmol L <sup>-1</sup> )	2.8 (0.8)*	332	-0.2 (0.7)	-0.4 (1.1)	386	0.059
Creatinine (μmol L <sup>-1</sup> )	80.4 (19.3)	385	+3.4 (22.4)	+0.5 (12.5)	461	0.281
BMI (kg m <sup>-2</sup> )	29.0 (5.5)	329	-0.1 (1.8)	-0.1 (1.6)	349	0.767

\**P* < 0.05 between SC and CAU group.Adjusted for: <sup>a</sup>baseline value, <sup>b</sup>duration of diabetes, <sup>c</sup>age, <sup>d</sup>insulin use, <sup>e</sup>gender.

BMI, body mass index; BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

with CAU. After 1 year, the percentage of patients who did not deteriorate was higher in the SC group for HbA1c, diastolic blood pressure, LDL cholesterol and BMI. This indicated that SC when compared with usual care had a more positive effect on the clinical outcomes. As the duration of the disease has an adverse effect on clinical outcome values, it can be argued that a stable outcome can be considered to be a positive effect. Therefore, even a small improvement in clinical outcomes, important for reducing cardiovascular risk, may have significant clinical implications for the diabetes population.

The SC studied here used a comprehensive approach. Multidisciplinary cooperation was supported with a registration programme, the health care professionals received besides education specific benchmark information, the patients received education and their participation was supported with the use of a diabetes passport. Other intervention studies that have included multiple components in primary care have investigated only short-term effects. The components most often used in these interventions were multidisciplinary cooperation [16–20], a registration programme [16–18], caregiver education [18–20] and patient education [17,19]. The effects of these interventions, albeit only considering the short-term effects, were consistent with our findings, with improvements found in one or more of the clinical outcomes important for cardiovascular risk. van Bruggen *et al.* found improvement in the process in diabetes care, but hardly in clinical outcomes [21].

There are some diabetes intervention studies that have investigated long-term effects, but these have not included multifaceted interventions. Ilag *et al.* and Renders *et al.* found no effects after 2 and 4 years [22,23]. Peters found an improvement only in HbA1c that was maintained after 3 years [24]. Olivarius *et al.* found improvement in HbA1c, blood pressure and cholesterol after 6 years and Ubink-Veltmaat *et al.* found improvement in blood pressure and cholesterol after 3 years [7,25]. The elements of these interventions consisted of patient [25] or caregiver education [7,22,23], multidisciplinary cooperation [22,24,25], a registration programme [23,24] or a combination of these, but not with three components or more. It seems more effects are found in multifaceted diabetes interventions.

## Strengths and limitations

The strengths of our study were the inclusion of patients involved in routine primary care, the comparatively long follow-up, the

inclusion of a comparable control group and the use of several clinical outcomes. The random selection of the sample and the implementation of the SC in an everyday setting enabled the results to be generalizable and applicable in a daily practice. A limitation may have been that the inclusion of practices that voluntarily participated in the SC programme may have held an above-average interest in research to improve quality of care. However, this is unlikely to have biased our findings because the control practices also voluntarily participated in a study on effects of adapted care. Moreover, for some clinical outcomes the SC group had more favourable baseline values. This suggested that in the SC group room for improvement was smaller, which may have led to some underestimation of the effects of SC.

## Conclusion

Structured diabetes care that consisted of multiple components showed a positive effect on clinical outcomes when compared with usual care. Considering these effects, SC can reduce complications in type 2 diabetes patients. Further research is needed to determine the cost-effectiveness of this type of SC and its effects on patient and health care professional experiences.

## Declaration

### Funding

Health Insurance Company De Friesland (De Friesland Zorgverzekeraar).

### Ethical approval

The design of the study was agreed upon by the local Medical Ethics Committee.

### Conflicts of interests

None.

## Acknowledgements

The authors would like to thank Marja Dijkman and Susanne Jurg for collecting the data, and the participating medical practices for

**Table 4** Effects of structured care after 1, 2 and 3 years compared with baseline

Variable	Baseline	1 year	n	P-value	2 years	n	P-value	3 years	n	P-value
HbA1c (%)	6.5	+0.2*	472	0.002	+0.1*	276	0.024	+0.1	98	0.140
Systolic BP (mmHg)	146.0	−2.7*	487	0.002	−4.5*	302	<0.001	−2.2	122	0.130
Diastolic BP (mmHg)	82.5	−1.7*	486	<0.001	−3.2*	302	<0.001	−4.1*	122	0.000
Total cholesterol (mmol L <sup>−1</sup> )	5.0	−0.2*	471	<0.001	−0.3*	271	<0.001	−0.4*	94	<0.001
HDL cholesterol (mmol L <sup>−1</sup> )	1.3	+0.03	422	0.093	+0.1*	246	<0.001	+0.2*	73	<0.001
LDL cholesterol (mmol L <sup>−1</sup> )	2.8	−0.2*	422	<0.001	−0.4*	246	<0.001	−0.5*	73	<0.001
Creatinine (μmol L <sup>−1</sup> )	79.9	+5.5*	447	<0.001	+4.1*	271	0.031	+5.4	88	0.067
BMI (kg m <sup>−2</sup> )	29.0	−0.1	338	0.197	−0.08	220	0.477	−0.3*	115	0.025

\* $P < 0.05$ .

BMI, body mass index; BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein.



their cooperation. The health insurance company De Friesland (De Friesland Zorgverzekeraar) provided financial support for this study.

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